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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,729	06/19/2001	Luis A. Davila	CRD-0938	2529

27777 7590 11/18/2003
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EXAMINER

LANDREM, KAMRIN R

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/18/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,729

Applicant(s)

DAVILA ET AL.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 1 and 9 are objected to because of the following informalities: It is unclear how a marker insert 804 can have a radius of curvature that is equal to the radius of curvature of the stent 100. Examiner believes that applicant intends to disclose that all of the inserts 804 in combination with the insert housing have a radius of curvature that is similar to that of the stent 100 (i.e. the markers are in alignment with stent and do not flare radially from the stent body). Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being anticipated by Globerman et al. (WO 97/33534) in view of Boatman et al. (USPN 5,632,771).

With regards to Figures 10-12, Globerman et al. disclose of a intraluminal medical device (Figures 10-12) made of a material such as nitinol, with a first collapsed diameter that is expandable to a second anchoring diameter, with at least one marker housing 29 and marker insert 25. As shown in Figure 11 the housing 29 and the insert 25 having an equal radii of curvature. As shown in Figure 2, the entire intraluminal device including the tubular member, housing 29, and insert 25, have equal radii of curvature. The marker insert (Fig. 11, Ref. Num.

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37) is substantially cylindrical, or as shown in Figure 4, may have a cone-like shape (pg. 5, line 3) to fit within the substantially tubular marker housing (Fig. 11, Ref. Num. 35). Nitinol is well known in the art as a superelastic alloy that is comprised of about 50% Nickel and the remainder Titanium. Globerman et al. further disclose that the marker housing is an integral part of the medical device structure (Figure 10), is made of the same material as the device and that the insert material is a different material such as tantalum (Page 3, Lines 5-6) and has a higher radiopacity than the device material. However, Globerman et al. lack the teaching of the at least one marker extending from the substantially tubular member. Boatman et al. teach of a flexible stent or tubular member with at least one marker connected to and extending from the tubular member (Figure 1, Ref. Numbers 41 and 42) to aid in the physician positioning the prosthesis at the site of an occlusion (3:25-27). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Globerman et al. to have the markers extend from the tubular member to aid in the positioning of the member.

Regarding claims 7 and 16, Globerman et al. disclose that the marker insert is secured to the marker housing by frictional engagement (Page 5, Lines 1-7).

Regarding claims 8 and 17, Globerman et al. disclose that the marker insert is secured in the marker housing by a protruding edge (Figure 9, Ref. Number 16).

Regarding claim 11, Globerman et al. disclose of a marker-housing embodiment that is substantially elliptical (Figure 8, Ref. Number 14).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman et al. (WO 97/33534) in view of Boatman et al. (USPN 5,632,771) and further in view of Imran (USPN 6,022,374).

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Regarding claim 15, Globerman et al. disclose a stent with radiopaque marker inserts, however they lack the teaching of the diameter of the inserts. Imran teaches of a stent with radiopaque markers that include an insert and a projection with a diameter of 0.015 inches (Column 3, Lines 17-29) to fit within the eyelet. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Globerman et al. to have marker inserts with a diameter of 0.02 inches to frictionally engage the marker housing.

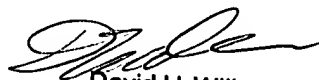
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 703-305-8061. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-308-3905.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Kamrin Landrem
Examiner
AU 3738


David H. Willse
Primary Examiner

KRL